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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,892	01/16/2004	Mary Aldritt	208-022US1	8476

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ALLISON JOHNSON, P.A.
LAKE CALHOUN EXECUTIVE CENTER
3033 EXCELSIOR BLVD., SUITE 467
MINNEAPOLIS, MN 55416

EXAMINER

HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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05/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/759,892	Applicant(s) ALDRITT ET AL.	
	Examiner Susan Coe Hoffman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed February 22, 2007 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claim 31 has been added.
3. Claims 1-31 are pending.
4. In the reply filed on July 11, 2006, applicant elected Group I, claims 1-19 and 31 without traverse.
5. Claim 20-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2006.
6. Claims 1-19 and 31 are examined on the merits.

Claim Rejections - 35 USC § 103

7. Claims 1, 3-10, 13, 15, 17, 18 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,299,925 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claimed invention is patentable over the reference because the reference does not specifically teach using cranberry extract in the effervescent tablet. However, the reference specifically claims using cranberry in the tablet (see claim 23). Thus, the use of cranberry in the effervescent tablet is encompassed by the patented subject matter and is considered a specific teaching of using cranberry in the effervescent tablet.

Applicant also argues that it would not have been obvious for a person of ordinary skill to arrive at the effervescent tablet with the claimed amount of cranberry extract and the claimed disintegration time. However, it has been well established that it is obvious to modify parameters that the art acknowledges are results effective variables. The reference teaches using a wide range of the fruit ingredient in claim 22. Thus, by using a range of amounts the art teaches a person of ordinary skill in the art that the amount of a specific ingredient can be varied. Furthermore, the reference teaches that it is important that the tablet fully dissolve in water (see column 3, lines 29-47 and column 5, lines 36-45). Thus, the variables that result in the tablet's water solubility would also be obvious to optimize because the reference acknowledges that this is an important variable of the effervescent tablet. The reference also teaches using a wide range of amounts for the binding agent (see claim 1). Thus, it would have also been obvious for an artisan to modify the amount of the binder in the reference composition. Therefore, new claim 35 is also considered obvious over the reference.

Applicant also argues that the reference does not teach the claimed invention because the reference does not teach that the tablet is able to measurably decrease the amount of bacteria in urine. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the reference is considered to teach a composition that is structurally the same as applicant's claimed composition, the composition motivated by the prior art would necessarily have to have the same characteristics. This is not an argument based on inherency. Inherency is appropriate when the prior art anticipates the claimed

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invention. The reference is not stated to anticipate. However, the reference does provide motivation to make the same product as claimed. The product made by the motivating factors in the reference would be the same as the claimed product. Thus, since the resulting product would be the same then the characteristics of this resulting product would also be the same.

8. Claims 11, 12, 14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,299,925 as applied to claims 1, 3-10, 13, 15, 17, 18 and 31 above, and further in view of US Pat. Pub. No. 2003/0161875 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that US '875 does not cure the deficiencies of US '925. However, US '925 is not considered deficient for the reasons discussed above.

Applicant also argues that US '875 and US '925 are not analogous art because US '875 is drawn to effervescent tablets that do not need water to dissolve while the tablets of US '925 are dissolved in water. This is not persuasive because both references are drawn to using making effervescent tablets that require an aqueous environment to dissolve. Thus, the references are considered analogous art. Furthermore, as discussed in the previous Office action, US '875 teaches using sorbitol and magnesium hydroxide as fillers in effervescent tablets. The reference teaches using these ingredient interchangeably with many of the same ingredients used in the tablet taught by US '925 (see paragraph 24 of '875 and paragraphs spanning columns 4 and 5 of US '925). Thus, the use of sorbitol and magnesium hydroxide in effervescent tablet was known in the art at the time of the invention. An artisan of ordinary skill would reasonably expect that sorbitol and magnesium hydroxide could be used to formulate the tablet taught by US '925 based on their functional equivalence with ingredients. This reasonable expectation of success would

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motivate the person of ordinary skill in the art to modify the tablet of US '925 to include sorbitol and magnesium hydroxide. Substituting well known ingredients for each other is not considered to render the claimed composition patentable over the prior art.

9. Claims 1-10, 13, 15-18 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,231,866 in view of US Pat. No. 6,299,925 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that there is no motivation to combine the two references together. Applicant argues that US '866 teaches away from using a composition that would dissolve such as that taught by US '925. However, US '866 teaches using the cranberry product in drinks (see column 4, lines 40-65). Thus, the products in US '866 would be incorporated into an aqueous solution in the same manner as the dissolved tablet in US '925. Thus, US '866 is not considered to teach away from using the effervescent tablet of US '925. Applicant also argues that it would not be obvious to combine the two references together because the using the effervescent tablet would cause the cranberry extract to be absorbed in the stomach which is not a goal of US '866. However, the means by which the cranberry is formulated in US '866 slows down the digestion of the cranberry (see column 5, lines 40-53). The inclusion of this cranberry product into the effervescent tablet would not alter this characteristic of the cranberry product. There is

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considered to be sufficient motivation to combine the references together. US '925 demonstrates that it was well known in the art at the time of the invention to use effervescent tablets to administer pharmaceutical substances that need to have improved bioavailability. US '866 teaches that cranberry seed extracts are in need of such as improvement. For this reason alone it is considered obvious to use effervescent tablets to formulate the cranberry seed extract of US '866.

10. Claims 11, 12, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,231,866 and US Pat. No. 6,299,925 as applied to claims 1-10, 13, 15-18 and 31 above, and further in view of US Pat. Pub. No. 2003/0161875 for the reasons set forth in the previous Office action.

Applicant argues against this rejection for the reasons set forth above. Thus, this rejection is still considered valid for the reasons discussed above.

11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963.

The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



5-12-07

Susan Coe Hoffman
Primary Examiner
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